



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Production (Soft Gel)	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Gelatin Cooking Vessel	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 OBJECTIVE:**

To lay down the procedure for Operation and Cleaning of Gelatin Cooking Vessel.

**2.0 SCOPE:**

This procedure is applicable for the Operation and Cleaning of Gelatin Cooking Vessel in Gelatin Manufacturing Area.

**3.0 RESPONSIBILITY:**

Technician/ Officer/Executive/Manager-Production.

Head of Department: To ensure execution & compliance.

Head QA: To ensure the compliance.

**4.0 PROCEDURE:**

**4.1 Operation**

4.1.1 Ensure cleanliness of the equipment and area.

4.1.2 Ensure that environmental conditions are within the limit as per given in the BMR.

Ensure that all the doors are closed and no chance of cross-contamination.

4.1.3 Ensure that Batch Manufacturing Record is available and all the entry is properly complete

4.1.4 till this stage.

4.1.5 Ensure that all containers are properly cleaned and labeled. It to be kept properly on pallet at a proper place.

4.1.6 Ensure that hot water, chilled water, purified water, vacuum and other utilities are required working as per specifications mentioned in BMR.

4.1.7 Ensure that "CLEANED" label affixed on the Gelatin Cooking Vessel.

4.1.8 Update the "AREA STATUS BOARD" duly filled and signature of production officer.

4.1.9 Take the line clearance from QA personnel as per SOP.

4.1.10 Remove "CLEANED" label from the Gelatin Cooking Vessel and affix the "STATUS LABEL" with duly filled and signature of production officer.

4.1.11 Cross check the weight of dispensed gelatin raw materials by weighing as per BMR.



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- 4.1.12 Switch "ON" the main electric supply of the Gelatin Cooking Vessel from the electric panel.
- 4.1.13 Enter the operation start time of Gelatin Cooking Vessel in equipment usage log book as per SOP.
- 4.1.14 Connect liquid and gelatin flaks transfer flexible hose pipe to inlet of Gelatin Cooking Vessel and other end to the material holding SS container.
- 4.1.15 Switch "ON" the vacuum pump and obtained vacuum pressure up to 600-700 mm of Hg.  
Obtained the Gelatin Cooking Vessel temperature Up to 65 °C to 80 °C by open hot water circulation as per requirement.
- 4.1.16 Transfer the glycerin and purified water into SS container as per Batch Manufacturing
- 4.1.17 Record add preservative in it and heat this mixture till complete dissolution.
- 4.1.18 Open the liquid inlet valve of Gelatin Cooking Vessel and transfer the Purified water, Glycerin, Sorbitol and preservative solution through connected flexible hose pipe with applying vacuum pressure with continue stirring.  
Transfer the gelatin flakes slowly into the Gelatin Cooking Vessel with continues stirring and
- 4.1.19 mix under vacuum as per mentioned in BMR. Maintain the stirrer speed (RPM 22±3).
- 4.1.20 Switch "OFF" the vacuum pump and release the vacuum pressure.
- 4.1.21 Check the temperature of the inside material of the Gelatin Cooking Vessel, it should not be more than 20 °C.
- 4.1.22 Mix the gelatin flakes with transferred liquids for 15 minutes or as per description of BMR.  
After proper mixing apply the initial vacuum for 15 minutes.
- 4.1.23 Switch "OFF" the vacuum pump and release vacuum pressure from the vessel.
- 4.1.24 Gradually raise the temperature of Gelatin Cooking Vessel up to 65 to 80 °C and keep continuous stirring at fast speed.
- 4.1.25 If the temperature is increase out of limit in higher, immediately stop the hot water circulation in Gelatin Cooking Vessel.
- 4.1.26 Reduce the stirrer speed up to 14±2 RPM during the de-aeration process.
- 4.1.27 Switch "ON" the vacuum pump and apply the final vacuum 600-700 mm of Hg to remove entrapped air from the gelatin mass as per mentioned in BMR.
- 4.1.28 After the de-aeration process transfer the prepared colour slurry into the Gelatin Cooking



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Vessel with continuous stirring and mix for 15 minutes.

- 4.1.30 Finally apply the vacuum 600 -700 mm of Hg for 15 minutes to remove generated entrapped air during colour mixing.
- 4.1.31 Switch “OFF” the vacuum pump and release the vacuum pressure.
- 4.1.32 Take the prepared gelatin mass sample in SS plate through the bottom discharge valve and check the gelatin mass consistency (thin and thickness of gelatin mass) and entrapped air bubble visually.
- 4.1.33 If air bubble is found in gelatin mass then start the vacuum pump and de-aerate the process till removal of entrapped air bubble from gelatin mass.
- 4.1.34 Filter the gelatin mass by sieve into preheated Gelatin Holding Tank.
- 4.1.35 Maintain the temperature of gelatin holding tank  $60 \pm 5$  °C till gelatin is to be used for Encapsulation.
- 4.1.36 Switch “OFF” the main supply of Gelatin Cooking Vessel.
- 4.1.37 Enter the operation complete time in equipment usage log book as per SOP.
- 4.1.38 Remove “STATUS LABEL” and affix the “TO BE CLEANED” label on the equipment with duly filled and signature of production officer.
- 4.1.39 Update the “AREA STATUS BOARD” with duly filled and signature of production officer.

### **4.2 Precaution**

- 4.2.1 Discharge valve shall be closed before material unloading.
- 4.2.2 Never leave the Gelatin Cooking Vessel with material over night.
- 4.2.3 Do not lean on the gelatin Cooking vessel during process.
- 4.2.4 During cleaning process never heat the water inside the Gelatin Cooking Vessel without opening the valve or lid.

### **4.3 CLEANING PROCEDURE**

#### **4.3.1 Cleaning procedure Type A**

**Change over from one batch to next batch of the same product and same potency and of similar product with ascending potency.**

- 4.3.1.1 Remove “TO BE CLEANED” label and affix “UNDER CLEANING” label to the machine



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with date and signature of the production officer as per SOP.

- 4.3.1.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.3.1.3 Close the bottom discharge valve of Gelatin Cooking Vessel and fill with purified water up to top of stirrer then start the stirrer at  $25 \pm 2$  RPM.
- 4.3.1.4 Start the hot water circulation in Gelatin Cooking Vessel and maintain the temperature 40 to 60 °C for 15 minutes with continue stirring.
- 4.3.1.5 Connect the hose pipe to bottom discharge valve of the Gelatin Cooking Vessel and drain the water.
- 4.3.1.6 Rinse the gelatin preparation vessel inner part with purified water through the spray valve given in the cooking vessel.
- 4.3.1.7 Switch “OFF” the main power supply from electric panel.
- 4.3.1.8 Clean the outer surface of the Gelatin Cooking Vessel with the dry lint free cloth.
- 4.3.1.9 Clean the area as per SOP.
- 4.3.1.10 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the Production Officer.
- 4.3.1.11 Record the cleaning complete time in equipment usage log book as per SOP.

**4.3.2 Cleaning procedure Type B**

**This is a cleaning procedure for Change over of product with different actives/ color/ descending potency or after maintenance of contact parts.**

- 4.3.2.1 Replace the “TO BE CLEANED” status label with “UNDER CLEANING” status label with date and signature of the Production officer and enter cleaning time in log book.
- 4.3.2.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.3.2.3 Start the hot water circulation in Gelatin Cooking Vessel and maintain the temperature 60 to 80 °C for 60 minutes with continue stirring.
- 4.3.2.4 Connect the hose pipe to bottom discharge valve of the Gelatin Cooking Vessel and drain the water.
- 4.3.2.5 Again fill the purified water with 1.0% v/v Teepol solution and rinse with the sufficient purified water. Inner surface of Gelatin Cooking Vessel clean with scrubber.
- 4.3.2.6 Repeat the above cleaning procedure till proper cleaning.



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- 4.3.2.7 After proper cleaning rinse the vessel with purified water through the spray valve to clean the traces of teepol solution.
- 4.3.2.8 Clean the outer surface of the Gelatin Cooking Vessel with the dry lint free cloth followed by 70 % v/v IPA solution.
- 4.3.2.9 Switch “OFF” the main power supply from electric panel.
- 4.3.2.10 Clean the area as per SOP.
- 4.3.2.11 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the Production officer.
- 4.3.2.12 Record the cleaning complete time in equipment usage log book as per SOP.

**5.0 ANNEXURE (S) :**  
Nil

**6.0 REFERENCE (S):**  
SOP: Procedure of filling of equipment log book.  
SOP: Procedure for area line clearance.  
SOP: Preparation, approval, distribution control, revision and destruction of standard operating procedure.

**7.0 ABBREVIATION (S) / DEFINITION (S):**  
SOP : Standard Operating Procedure  
MM Hg : Millimeter of Mercury.  
RPM : Rotation Per Minute  
IPA : Iso Propyl Alcohol  
v/v : Volume / Volume  
NA : Not Applicable  
BMR : Batch Manufacturing Record



# PHARMA DEVILS

PRODUCTION DEPARTMENT

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## REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---